

ASSEMBLY BILL

No. 995

Introduced by Assembly Member Block

February 27, 2009

An act to amend Section 1639.01 of, and to add Section 1643.3 to, the Health and Safety Code, relating to tissue banks.

LEGISLATIVE COUNSEL'S DIGEST

AB 995, as introduced, Block. Tissue bank licensing.

Existing law requires the Department of Health Care Services to establish regulations, as specified, governing the operation and maintenance of tissue banks licensed in California. Existing law allows for the revocation or suspension of a tissue bank's license for specified reasons. Violation of these provisions is a misdemeanor.

This bill would require the collection, processing, storage, or distribution of human tissue by licensed tissue banks and tissue for use in California to comply with the 12th edition of Standards for Tissue Banking as published by the American Association of Tissue Banks. This bill would also allow the department to impose on licensed and unlicensed tissue banks, as an alternative to suspension or revocation of a tissue bank's license, a civil administrative penalty of up to \$100 per infraction or immediate jeopardy, up to a maximum amount of \$3,050 per day of noncompliance.

Because the bill would make changes to the definition of a crime, it constitutes a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1639.01 of the Health and Safety Code
2 is amended to read:

3 1639.01. (a) ~~Notwithstanding Section 1639, the state~~
4 ~~department shall adopt, on or before July 1, 2004, rules and~~
5 ~~regulations governing licensed tissue banks engaged in the~~
6 ~~collection of human musculoskeletal tissue, skin, and veins for~~
7 ~~transplantation in humans. The regulations shall be substantially~~
8 ~~based upon the criteria used by tissue bank trade associations in~~
9 ~~their respective accreditation processes including, but not limited~~
10 ~~to, those of the Eye Bank Association of America and the American~~
11 ~~Association of Tissue Banks, and the scientific and technical data~~
12 ~~submitted by individual tissue banks~~ *no person shall engage in*
13 *the collection, processing, storage, or distribution of human tissue*
14 *unless the tissue is collected, prepared, labeled, stored, and*
15 *distributed in accordance with the standards set forth in the 12th*
16 *edition of Standards for Tissue Banking as published by the*
17 *American Association of Tissue Banks and in effect on May 1,*
18 *2008. These shall be the standards for all licensed tissue banks*
19 *operating in California or providing tissue to be used in California.*

20 (b) ~~Regulations adopted by the state department, pursuant to~~
21 ~~subdivision (a), shall include minimum standards for all of the~~
22 ~~following:~~

23 (1) ~~Safe preservation, transportation, storage, and handling of~~
24 ~~tissue acquired or used for transplantation.~~

25 (2) ~~Testing of donors to determine compatibility when~~
26 ~~appropriate.~~

27 (3) ~~Testing or assessment of donors to prevent the spread of~~
28 ~~disease through transplantation.~~

29 (4) ~~Equipment.~~

30 (5) ~~Methods.~~

31 (6) ~~Personnel qualifications.~~

1 ~~(7) Any other area concerning the operation or maintenance of~~
2 ~~a tissue bank, not inconsistent with this chapter, as may be~~
3 ~~necessary to carry out this chapter.~~

4 ~~(e) On or before July 1, 2003, the department shall report to~~
5 ~~the appropriate policy and fiscal committees of the Legislature~~
6 ~~regarding the status of the proposed regulations.~~

7 SEC. 2. Section 1643.3 is added to the Health and Safety Code,
8 to read:

9 1643.3. As an alternative to revocation or suspension of a
10 license issued under this chapter, the department may impose an
11 alternative civil administrative penalty of up to one hundred dollars
12 (\$100) per infraction or immediate jeopardy, up to a maximum
13 amount of three thousand fifty dollars (\$3,050) per day of
14 noncompliance. This penalty may be imposed only after notice
15 and an opportunity to respond in accordance with Section 100171
16 and may also be imposed upon nonlicensed tissue banks.

17 SEC. 3. No reimbursement is required by this act pursuant to
18 Section 6 of Article XIII B of the California Constitution because
19 the only costs that may be incurred by a local agency or school
20 district will be incurred because this act creates a new crime or
21 infraction, eliminates a crime or infraction, or changes the penalty
22 for a crime or infraction, within the meaning of Section 17556 of
23 the Government Code, or changes the definition of a crime within
24 the meaning of Section 6 of Article XIII B of the California
25 Constitution.